



Patent
Attorney's Docket No. 031786-046

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of) **BOX: RCE**
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Stephen M. BOYLE et al.) Group Art Unit: 1645
)
Application No.: 09/692,623) Examiner: Jennifer E. Graser
)
Filed: October 20, 2000) Confirmation No.: 2200
)
For: AN OVER-EXPRESSING)
HOMOLOGOUS ANTIGEN VACCINE)
AND A METHOD OF MAKING THE)
SAME)

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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

No additional fee is required as this IDS is submitted concurrently with a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114.

Copies of the listed documents were previously submitted with the Reply filed February 6, 2003 and have been acknowledged by the Examiner as placed in the file (but not considered) in the Official Action mailed February 25, 2003. Accordingly, copies of the listed documents are not included.

Further, Applicants provide the Examiner with the following comments regarding some of these references.


Sanchez et al. (*PNAS* 86:481-485 (1989)) and Sanchez et al. (*FEBS Lett.* 241:110-114 (1988)) disclose recombinant *V. cholerae* strains that overexpress CTB and CTB-fusion proteins for purification and potential use as killed oral cholera vaccines.

Lebens et al. (*Biotechnology* 11:1574-1578 (1993)) disclose the use of the CTB/LTB fusion protein as described in the Sanchez et al. publications for vaccine development. Lebens et al. overexpress the CTB antigen in order to produce large amounts of this antigen for purification and subsequent use in a subunit vaccine.

Neither of the Sanchez et al. publications nor the Lebens et al. publication disclose the use of an attenuated or avirulent strain of an otherwise pathogenic organism as a vaccine, but rather merely describe means of preparing antigenic proteins to be used in vaccines. Additionally, none of these publications suggest the use of *Brucella*, a Cu/Zn SOD gene, or a GroEL or GroES gene in creating the vaccine used in the method of the presently claimed invention. Accordingly, these publications are not believed to render the presently claimed invention unpatentable.

To assist the Examiner, the cited documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,
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